

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Patent Application of:	:	
Henrich CHENG	:	
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Conf. No.: 2231	:	Group Art Unit: 3734
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Appln. No.: 10/766,530	:	Examiner: Michael G. Mendoza
	:	
Filing Date: January 29, 2004	:	Attorney Docket No.: 681942-1US
	:	(IC0011/HC0001US)

Title: METHOD AND MIXTURE FOR NERVE ROOT REPAIR

REQUEST FOR RECONSIDERATION

This is in response to the final Office Action dated August 4, 2009 (Paper No. 20090730) concerning the above-identified application. This response is being timely submitted by the current deadline of November 4, 2009.

Applicants wish to thank Examiner Mendoza for the courteous telephone interview of September 2, 2009, among the Examiner, the undersigned attorney and Dr. Henrich Cheng, the inventor and applicant of the present application. This Request for Reconsideration summarizes the interview, at the end of which the Examiner indicated his intention, subject to discussion with his supervisor, to remove the primary reference in the obviousness rejection under 35 U.S.C. § 103(a), which is the only outstanding rejection, namely, Cheng et al. U.S. Patent 6,235,041 (hereinafter "Cheng '041"), of which Dr. Cheng was a primary inventor.

During the interview, the undersigned attorney and Dr. Cheng pointed out that the language of the Office Action at section 5 bridging pages 2 and 3, discussing the Examiner's view of Cheng '041 revealed that there was a misunderstanding of the disclosure and teaching of Cheng '041. The relevant portion of section 5 states:

As to claims 1 and 2, Cheng et. al. teaches a method of functionally connecting a portion of the peripheral nervous system of a vertebrate to a portion of the central or peripheral nervous system of the vertebrate ... forming an attachment between the portion of the peripheral

nervous system and the portion of the central or peripheral nervous system of the vertebrate (col. 1, lines 27-34). [Emphasis added]

The undersigned attorney pointed out the misinterpretation, particularly in view of the disclosure and drawings of Cheng '041 as a whole, based on the reference to the quoted statement from Cheng '041's column 1, lines 33-34: "Nerve bridges were created between the peripheral nerves and the spinal cord."

During the interview, it was explained that Cheng '041 does not connect any portion of the peripheral nervous system with (a) any portion of the central nervous system or (b) any portion of the peripheral nervous system. The present invention in independent claims 1 and 12 and their dependent claims is directed to a method of functionally connecting a viable, living portion of the peripheral nervous system of a living vertebrate to a viable, living portion of the central or peripheral nervous system of that living vertebrate. Claim 1 refers broadly to connecting portions of the peripheral or central nervous systems, while claim 12 refers to reconnecting an avulsed cervical nerve root (a portion of the peripheral nervous system) to the spinal cord (a portion of the central nervous system).

What is clearly missing from, but what was mistakenly inferred in the Examiner's interpretation of the quoted language from Cheng '041 is the important word "system," regarding the "peripheral nerves." The Examiner's attention was directed to Figs. 1a and 1b of Cheng '041 showing the use of a non-viable bridge or conduit, that may be a removed section or sections of a non-viable peripheral nerve or nerves, among other devices, placed between portions of a spinal column (a portion of the central nervous system), to connect separated parts of the spinal column, using the fibrin glue composition. Thus, in Cheng '041, where a portion of a peripheral nerve was removed from a different or perhaps the same vertebrate, upon removing that portion, the portion or section of the removed peripheral nerve was no longer viable and served as an inanimate, non-viable conduit or tube, and therefore, is called a "device" in Cheng '041, for connecting and restoring function only within the spinal cord or other portion only of the central nervous system.

The Examiner's attention also was directed to column 1, line 36, to column 3, line 20, and column 5, lines 16-62, in Cheng '041, disclosing the use of other types of bridging structures or tubes or even plates, besides a removed section or portion of a peripheral nerve or nerves, such as several different types of bio-compatible synthetic polymers (see, for example column 5, lines 16-38). Transplanted nerve bundles or Schwans cells within the tubes or plates promote

nerve growth of the central nervous system that is being repaired (see, for example, column 5, lines 58-62 of Cheng '041).

During the interview, the use of the non-viable materials to connect broken portions of the spinal cord in Cheng '041 was contrasted with the method of the present invention of using the fibrin glue composition for connecting viable portions of the peripheral nervous system with other viable portions of the peripheral nervous system or viable portions of the central nervous system, such as the spinal cord, in the present application.

The Examiner's attention was directed to Figs. 3A, 3C and 3D of the present application to show the difference compared to Figs. 1a and 1b of Cheng '041. The photomicrographs of these figures are explained at page 5 of the present application and relate to the procedures performed as explained at page 8 to the top of page 9 of the present application. During the interview, it was explained that Fig. 3A shows at the arrow the surgical separation of a portion of an untreated, control rat's spinal cord. Fig. 3C shows a peripheral nerve connected to the spinal cord in a rat treated according to the present invention, where the peripheral nerve appears like a separate vessel extending from about the 8 o'clock position to about the 12 o'clock position. Dr. Cheng explained that the effective, functional connection in Fig. 3C is shown at about the 8 o'clock position with respect to the box in Fig. 3C. He further explained that the dark area of Fig. 3D of the present application showed that the neurons of the cells of the different nervous systems were connected and also explained that because of the connection, nerve connection to the muscles and the function of the muscles was restored, as disclosed in the application.

Following the explanations of the differences between the present invention and Cheng '041, the Examiner indicated that he better understood such differences and planned to remove Cheng '041 as a reference, since it does not disclose connecting a portion of the peripheral nervous system to another portion of the peripheral nervous system or to a portion of the central nervous system.

The undersigned attorney then pointed out that the secondary reference, Schenck et al. U.S. Patent 4,553,542 ("Schenck"), does not overcome the deficiencies in Cheng '041. As previously noted in responses to prior Office Actions, Schenck taught an anastomosis device and method for using it to join a tubular anatomical structure that is supported with the body by connective tissue and has a prepared open end to a second anatomical structure, such as blood vessels, fallopian tubes, ureters, vas deferens and outer nerve sheaths (see abstract and claim 1).

The use of Schenck's encircling anastomosis device would not be useful for, and therefore is totally irrelevant to a method for connection between nerves, which are not hollow tubes. What might work for connecting nerve sheaths may not be effective in connecting nerves. Moreover, Cheng '041 and Schenck, are not properly combinable, because of the different structure and functions of nerves involved in Cheng '041, compared to the anatomical structures repaired in Schenck. Even assuming only for the sake of argument that these references are properly combinable, as refuted previously, the combination does not teach or suggest the presently claimed invention.

Since Cheng et al., when fairly viewed in its entirety, would disclose to one skilled in the art only the repair of the central nervous system, and not connecting the central nervous system with the peripheral nervous system or repairing defects and making connections only within the peripheral nervous system, it would not have been obvious to such a skilled person to make such repairs and connections as claimed in the present invention, even in view of Schenck.

Reconsideration and withdrawal of the rejections and an early Notice of Allowance are respectfully requested.

If further discussion would help advance the prosecution of this application, the Examiner is invited to contact the undersigned attorney by telephone.

Respectfully submitted,

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Sept-25, 2009
(Date)

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